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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/936,170	Applicant(s) ERIC ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed December 19, 2005 is acknowledged and has been entered. Claims 1-17 have been amended. Claim 18 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Currently, claims 1-18 are pending. Claims 1-17 are under examination.

Election/Restrictions

2. Applicant requests reconsideration and rejoinder of claim 18 with elected Group I and argues that Groups I and II are so closely linked and drawn to the same inventive concept, namely the use of intracellular immunoglobulins; hence search and examination of both groups together would not pose serious burden on the Examiner.

Contrary to Applicant's argument, Group II is drawn to method of preparing intracellular immunoglobulins as opposed to Group I which is drawn to use of intracellular immunoglobulins; hence, Groups I and II are rendered independent and distinct as they have separate structural requirements which require separate fields of search, i.e. generating immunoglobulins versus using selected immunoglobulins in a functional assay. Literature search for each method is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive. Because these

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inventions are distinct for the reasons given above, have acquired a separate status in the art requiring separate search, examination, and undue burden to Examiner, restriction for examination purposes as indicated is proper.

The restriction requirement is deemed proper, and is therefore made FINAL.

Information Disclosure Statement

3. The references cited in the Search Report, filed 9/10/01 with the 371 Application, have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO/SB/08A and 08B form, must be filed within the set period for reply to this Office action.

Withdrawn Rejections

4. All rejections and objections not reiterated herein, have been withdrawn.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required. In this case, the recitation of "a specific interaction" lacks antecedent basis in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step a) lacks clear antecedent basis in reciting, "the specific interaction". It is further unclear how the recitation of "specific interaction" is distinct and functionally related to the recitation of "stable interaction" since both interactions appear to lead to generation of a signal. Accordingly, it is unclear what Applicant intends to encompass in reciting, "specific interaction". See also claim 3.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gargano et al. (From Phage Libraries to Intracellular Immunization, Intracellular Antibodies: Development and Applications (1997) Chapter 10, pages 174-186)) for reasons of record.

Response to Arguments

8. Applicant's arguments filed December 19, 2005 have been fully considered but they are not persuasive.

A) Applicant argues that Gargano et al. does not anticipate the claimed invention because it fails to teach each and every element in the claimed invention. Applicant specifically contends that Gargano et al. disclose a method wherein one intracellular antibody is already known and gives a positive signal in the assay. Applicant further argues that Gargano et al. do not teach or suggest 1) that their assay can be used to select intracellular antibodies, and that their assay can provide analysis of the capacity of the antibodies to bind intracellularly, since their intracellular behavior is not known.

In response, Applicant's argument is not persuasive because the recitation of "wherein an immunoglobulin is associated with the first molecule, and wherein an intracellular target is associated with the second molecule ...; and assessing the intracellular binding" in claim 1, does not appear to exclude that the *antibody is known*, a teaching which Applicant contends, is taught in the method of Gargano et al. Alternatively, claim 1 does not specifically and clearly define that *the immunoglobulin and its capacity to bind is unknown*, a teaching which Applicant contends, is lacking in the method of Gargano; thus rendering it distinct from the claimed invention.

Further in contrast to Applicant's argument, the teaching of Gargano et al. appears to read on the claimed invention in teaching that the method determines efficient binding between intracellular immunoglobulins (scFv fragment) expressed in a yeast two hybrid format and corresponding target antigens in an intracellular

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environment (yeast cells), and isolates and selects immunoglobulins which bind successfully (see page 176, second full paragraph, and Figure 10.1). Gargano et al. at page 176, second full paragraph, specifically provides extending the method to an experimental design tailored to select polyclonal antibody populations on the basis of their binding to a specific antigen in an intracellular environment for subsequent validation and exploitation of their function in functional intracellular experiments. Accordingly, the rejection of claims 1-17 as being anticipated by Gargano et al. is being maintained.

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
March 14, 2006



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641
3/17/06